

Before the  
Administrative Hearing Commission  
State of Missouri



MISSOURI BOARD OF PHARMACY,

Petitioner,

vs.

JEFFERSON CITY APOTHECARY,

Respondent.

No. 12-0697 PH

**DECISION ON RECONSIDERATION**

Jefferson City Apothecary's ("the Apothecary") pharmacy permit is subject to discipline for violation of drug regulations of this state, including lawful regulations adopted pursuant to Chapter 338 RSMo.

**Procedure**

On April 20, 2012, the Missouri Board of Pharmacy ("the Board") filed a complaint seeking our determination that there is cause to discipline the Apothecary's permit. On June 1, 2012, the Apothecary filed a motion for more definite statement. We granted the motion on July 6, 2012. On July 16, 2012, the Board filed an amended complaint, and on July 25, 2012, the Apothecary answered the amended complaint. On January 15, 2013, Uldis Pironis ("Pironis") filed a motion to consolidate this case with *Missouri Board of Pharmacy v. Uldis Pironis*, number 12-0699 PH, for the hearing of the two cases. On January 17, 2013, we granted

Pironis’s motion. On March 6, 2013, we convened a hearing. Loretta Schouten represented the Board. Johnny K. Richardson and Jamie J. Cox represented Pironis.

This case became ready for our decision when Pironis and the Apothecary (collectively, “Respondents”) filed their last written argument on April 25, 2013. On September 9, 2013, we issued a combined decision in this case and case number 12-0699 PH, in which we struck the Board’s pleadings in the two cases as a sanction. On September 27, 2013, the Board filed a motion to reconsider that decision, asking us to reinstate the portions of the pleadings in the two cases that related to the Board’s 2011 investigations of Pironis and the Apothecary.<sup>1</sup> Respondents filed suggestions in opposition to the motion on October 4, 2013. We granted the motion to reconsider on October 7, 2013.

Commissioner Marvin O. Teer, Jr., having read the full record including all the evidence, renders the decision on reconsideration.<sup>2</sup>

### **Findings of Fact**

1. At all relevant times, the Apothecary held a current and active Missouri pharmacy permit.<sup>3</sup>
2. At all relevant times, the Apothecary was a limited liability company.
3. Pironis was the pharmacist-in-charge (“PIC”) of the Apothecary at all relevant times.
4. At all relevant times, the Apothecary compounded and dispensed drugs and medicines.

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<sup>1</sup> As noted below under “Pleading matters,” the Board’s cases against Pironis and the Apothecary arose from two discrete investigations—one based on an inspection conducted by the Board’s inspectors in 2010, and the other based on the incidents, which occurred on April 29, 2011, that we describe in our Findings of Fact below.

<sup>2</sup> Section 536.080.2, RSMo 2000; *Angelos v. State Bd. of Regis’n for the Healing Arts*, 90 S.W.3d 189, 192-93 (Mo. App., S.D. 2002). Statutory references are to RSMo 2012 Supp. unless otherwise indicated.

<sup>3</sup> Tr. 122.

5. For about 13 years prior to the date of the hearing, Pironis employed a pharmacy technician named Ginger Stratman.

6. Because he knew he would not be in Jefferson City on April 29, 2011, Pironis arranged, before that date, for another pharmacist to work in the Apothecary.

7. However, on April 29, 2011, the other pharmacist did not report for work due to a family illness. When informed that the other pharmacist had not reported for work, Pironis instructed Apothecary staff to close the Apothecary, but to leave the doors open so that customers could come in and learn why they could not pick up their prescriptions.

8. On that day, Stratman was working at the Apothecary when the Apothecary received a call from Dr. Tamara Hopkins, who requested that the Apothecary prepare a chemotherapy drug, Vidaza, for intravenous administration.

9. Stratman contacted Pironis to tell him of Dr. Hopkins' request.

10. Pironis contacted Hopkins and told her that the Apothecary could not compound the drug because there was no pharmacist there to check it.

11. Hopkins replied that she needed the drug right away. Pironis suggested that Stratman could compound the drug at Dr. Hopkins' office, but it was decided that Stratman would compound the drug at the Apothecary and take it to Dr. Hopkins' office.

12. Stratman compounded the drug and delivered it to Dr. Hopkins' office.

13. At all relevant times, Pironis and Stratman were agents of the Apothecary.

14. The Board first learned of the above-stated events that occurred on April 29, 2011 ("the April 29 incident") from information it had received that someone in the Apothecary was practicing pharmacy without a license when a pharmacist was not on duty.

15. As a result of receiving that information, Sid Werges, an investigator for the Board, went to the Apothecary on May 2, 2011, where he learned of the April 29 incident.

## Pleading Matters

The Board's amended complaint against the Apothecary alleges, in some detail, the following actions, all of which arose from an inspection of the Apothecary by the Board's inspectors on September 21, 2010:

- Patient-specific compounded prescriptions were returned to the Apothecary's active inventory for future dispensing without preparing batch logs, in violation of 20 CSR 2220-2.400(7)(A)(D);<sup>4</sup>
- Labeling a compound of Guaifenesin 300mg/Phenylephrine 10mg as "SR" for sustained release without analytical data to prove it had sustained release characteristics, in violation of 20 CSR 2220-2.400(12);<sup>5</sup>
- Compounding a number of products for office stock, in violation of 20 CSR 2220-2.400(12);<sup>6</sup>
- Compounding 200-capsule batches of Policosanol 30mg, a commercially available product, without documented authorization in violation of 20 CSR 2220-2.400(9);<sup>7</sup>
- The expiration dates for ingredients used in compounded products were shorter than the expiration dates for a number of compounded products, in violation of 20 CSR 2220-2.400(4), (8)(A);<sup>8</sup>
- The Apothecary dispensed prescriptions from misbranded lots and after the expiration dates of the ingredients for several products (no regulation was cited that these actions allegedly violated);<sup>9</sup>
- The Apothecary used expired ingredients to compound drug products in violation of §§ 196.015, 196.095, 196.100 RSMo, and 20 CSR 2220-2.400(8)(A) with regard to several products;<sup>10</sup>
- The Apothecary dispensed prescriptions from misbranded lots in violation of §§ 196.015, 196.095, 196.100 RSMo, and 20 CSR 2220-2.400(8)(A) with regard to several products;<sup>11</sup> and
- The Apothecary dispensed prescriptions from misbranded lots in violation of §§ 196.015, 196.095, 196.100 RSMo, and 20 CSR 2220-2.400(8)(A) with regard to several products.<sup>12</sup>

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<sup>4</sup> Amended complaint ¶ 10a. All references to the CSR are to the Missouri Code of State Regulations as current with amendments included in the Missouri Register through the most recent update.

<sup>5</sup> Amended complaint ¶ 10b.

<sup>6</sup> *Id.* ¶ 10c.

<sup>7</sup> *Id.* ¶ 10d.

<sup>8</sup> *Id.* ¶ 12.

<sup>9</sup> *Id.* ¶ 13.

<sup>10</sup> *Id.* ¶ 14.

<sup>11</sup> *Id.* ¶ 15.

<sup>12</sup> *Id.* ¶ 16.

However, due to the Board's failure to comply with Respondents' discovery request regarding the September 21 inspection, we barred the Board from presenting evidence at the hearing regarding that inspection. As a result, the Board abandoned the allegations set out above.

### **Evidentiary Matters**

Respondents objected to Werges' testimony regarding statements allegedly made by Stratman and another Apothecary employee, Jessica Dickey, to him. The Board argued that such statements were admissible under the employee/agent exception to the hearsay rule, citing among other authorities *State Hwy. Comm'n v. Howard Const. Co.*<sup>13</sup> Here is what the Court of Appeals said in that case:

[A] narrative statement by an employee of past events is not admissible against the employer unless the admissions are made within the scope of the employee's employment; *and* to be within the scope of his duties, the employee usually must have some executive capacity.<sup>[14]</sup>

(Emphasis added.) In this case, while it is arguable as to whether Stratman's statements were made within the scope of her employment, the Board failed to show that she had any executive capacity.

The Board also argued that Respondents failed to timely object to Werges' statement about what Stratman and Dickey said, citing the portions of the transcript at p. 64, lines 5-13, and p. 65, lines 1-11. We reproduce the relevant portion of the transcript here, starting at p. 63, line 22:

Q Okay. So what information did you learn about what occurred on April 29?

A She told me that Uldis Pironis, the pharmacist-in-charge, was in Chicago and that he had made arrangements for another pharmacist to work on April 29; but because of illness in his family, he was not able to show up. And so the technicians were in

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<sup>13</sup> 612 S.W.2d 23 (Mo. App., W.D. 1981).

<sup>14</sup> *Id.* at 26.

communication with Mr. Pironis. And Ms. Stratman told me that Mr. Pironis told her to, you know, close the pharmacy but leave the doors open so people could come in, and they could explain to them about, you know, their prescriptions and why they couldn't pick them up, because there was no pharmacist on duty. And then she began to explain to me what she and the other technician, Jessica Dickey, did while they were there that day. She told me that Dickey did some –

MR. RICHARDSON: Your Honor, I'm going to object that this calls for hearsay.

The rules regarding timeliness of an objection have been stated as follows:

To preserve an alleged error relating to the overruling of an objection, “it is necessary that an objection be timely made, and usually this necessitates that the objection be made at the earliest possible opportunity in the progress of the case so that the trial judge may have an opportunity to correct, or set right, that which is later to be claimed to be wrong.” An untimely objection amounts to a waiver of that objection. Only when there is no opportunity to object to questionable testimony—e.g., the witness responded too quickly to an improper question for an objection to be immediately interposed—is a later objection permissible.<sup>[15]</sup>

In *Oak Bluff Condo. Ass’n*, the case cited immediately above, counsel asked the witness one question that elicited a hearsay response, and then asked three more questions before opposing counsel raised a hearsay objection. The Court of Appeals held that the trial court did not err in overruling the objection as untimely.<sup>16</sup>

In this case, however, counsel for Respondents objected while Werges was answering the first question—admittedly, with a narrative answer that included three hearsay statements (“Ms. Stratman told me that...,” “And then she began to explain to me...,” and “She told me that...”), but we must decide whether the objection was made later than “...the earliest possible opportunity in the progress of the case so that the trial judge may have an opportunity to correct,

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<sup>15</sup> *Oak Bluff Condo. Ass’n v. Oak Bluff Partners, Inc.*, 263 S.W.3d 714, 719-20 (Mo. App., S.D. 2008) (internal citations omitted).

<sup>16</sup> *Id.* at 721.

or set right, that which is later to be claimed to be wrong.” We think Respondents’ objection was timely by that standard. Therefore, we sustain Respondents’ objection to Werges’ statement.

### **Conclusions of law**

We have jurisdiction to hear the Board’s complaint.<sup>17</sup> The Board has the burden of proving by a preponderance of the evidence that the Apothecary committed an act for which the law allows discipline.<sup>18</sup>

#### The Apothecary’s Liability for the Actions of Pironis

The Board’s amended complaint alleges that the Pharmacy itself took the actions that would submit its permit to discipline. For example, it alleges that “Licensee<sup>19</sup> allowed technicians to work in the pharmacy and prepare and/or dispense chemotherapy compounds without a pharmacist present....”<sup>20</sup> The amended complaint further alleges, “Licensee had formed a relationship of professional trust and confidence with patients....”<sup>21</sup>

In its brief, the Board argues two grounds for holding the Apothecary liable for the actions of others. First, it argues that the Apothecary, as a limited liability company, was liable for Pironis’s actions pursuant to § 347.065.1<sup>22</sup> because he was its owner. Section 347.065.1 is found in Chapter 347, “Limited liability companies—merger and consolidation of business organizations,” and provides:

*Except as provided in subsection 2 of this section, every member is an agent of the limited liability company for the purpose of its business and affairs, and the act of any member, including, but not limited to, the execution of any instrument, for apparently carrying on in the usual way of the business or affairs of the limited liability company of which he is a member binds the limited liability company, unless the member so acting has in fact no authority to act for the limited liability company in the particular matter, and*

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<sup>17</sup>Section 338.055.2.

<sup>18</sup>*Missouri Real Estate Comm’n v. Berger*, 764 S.W.2d 706, 711 (Mo. App., E.D. 1989).

<sup>19</sup>The amended complaint refers to the Apothecary as “Licensee.” Amended complaint ¶ 3.

<sup>20</sup>Amended complaint ¶ 17.

<sup>21</sup>*Id.* ¶ 19.

<sup>22</sup>RSMo 2000.

the person with whom he is dealing has knowledge of the fact that the member has no such authority.

(Emphasis added.) Subsection 2 provides:

2. If the articles of organization provide that management of the limited liability company is vested in one or more managers:

(1) No member, acting solely in his capacity as a member, is an agent of the limited liability company; and

(2) Every manager is an agent of the limited liability company for the purpose of its business and affairs, and the act of any manager for apparently carrying on in the usual way of the business or affairs of the limited liability company of which he is a manager binds the limited liability company, unless the manager so acting has, in fact, no authority to act for the limited liability company in the particular matter, and the person with whom he is dealing has knowledge of the fact that the manager has no such authority.

Pironis indeed was the owner of the Apothecary.<sup>23</sup> And, while the Missouri limited liability company statutes do not specifically set it out, a limited liability company's owners are, ordinarily, its members, and *vice versa*.<sup>24</sup> However, section 2 states an exception to the general rule of agency liability stated in section 1, if the limited liability company is managed by one or more managers. Because the Board failed to present any evidence as to whether the Apothecary was so managed, we cannot impute liability to the Apothecary for Pironis' actions pursuant to this statute.

In its brief, the Board also argues that the Apothecary was liable as a principal for any breach of duty committed in its name.<sup>25</sup> The Board cites *Fowler v. Park Corp.*<sup>26</sup> in support. However, the Board failed to plead this ground in its amended complaint. Therefore, we do not consider it.

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<sup>23</sup> Tr. 105.

<sup>24</sup> See *JB Contracting, Inc. v. Bierman*, 147 S.W.3d 814, 819 (Mo. App., S.D. 2004) (sole member of LLC referred to both as "member" and "owner").

<sup>25</sup> Board's brief ¶ 41.

<sup>26</sup> 673 S.W.2d 749 (Mo. banc 1984).



### Grounds for Discipline

The Board alleged that the Apothecary's permit was subject to discipline under the following provisions of § 338.055.2:

The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621 against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

\* \* \*

(5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

\* \* \*

(10) Assisting or enabling any person to practice or offer to practice any profession licensed or regulated by this chapter who is not registered and currently eligible to practice under this chapter;

\* \* \*

(13) Violation of any professional trust or confidence;

\* \* \*

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government[.]

#### § 338.055.2(5)- Incompetency, Misconduct, Gross Negligence, Misrepresentation, and Fraud

##### *Incompetency*

Incompetency is a general lack of professional ability, or a lack of disposition to use an otherwise sufficient professional ability, to perform in an occupation.<sup>27</sup> We follow the analysis of incompetency in a disciplinary case from the Supreme Court, *Albanna v. State Bd. of Reg'n for the Healing Arts*.<sup>28</sup> Incompetency is a “state of being” showing that a professional is unable or unwilling to function properly in the profession.<sup>29</sup> We find no lack of professional ability in Pironis’s actions—and by imputation, no lack of professional ability by the Apothecary. To the contrary, Pironis had extensive training and experience in pharmacy, as was recognized by his speaking engagements at continuing education and other seminars, as well as his role as an adjunct professor in schools of pharmacy. Specifically, in this case, he was well aware of the issues involved with compounding and dispensing drugs without his being present during those events and discussed them knowledgably with Dr. Hopkins. Neither do we find any lack of professional ability with regard to the Apothecary-- which would, if found, subject Pironis’ license to discipline due to his being pharmacist-in-charge of the Apothecary.

On the other hand, Pironis’ allowing Stratman to compound the drug does show a lack of disposition to use his otherwise professional ability. However, this isolated incident does not show a “state of being” showing his inability or unwillingness to function properly in his profession. Therefore, we find no ground for discipline against the Apothecary for incompetency.

### *Misconduct*

Misconduct means “the willful doing of an act with a wrongful intention[;] intentional wrongdoing.”<sup>30</sup> While the Board makes much of Pironis’s alleged willfulness in his actions, the

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<sup>27</sup> *Tendai v. Missouri State Bd. of Reg’n for the Healing Arts*, 161 S.W.3d 358, 369 (Mo. banc 2005).

<sup>28</sup> 293 S.W.3d 423 (Mo. banc 2009).

<sup>29</sup> *Id.* at 435.

<sup>30</sup> *Missouri Bd. for Arch’ts, Prof’l Eng’rs & Land Surv’rs v. Duncan*, No. AR-84-0239 (Mo. Admin. Hearing Comm’n Nov. 15, 1985) at 125, *aff’d*, 744 S.W.2d 524 (Mo. App., E.D. 1988).

Board failed to provide any evidence of the other element of the definition, i.e., wrongful intention. We find no wrongful intention, either by Pironis or by the Apothecary itself. Therefore, we find no ground for discipline against the Apothecary for misconduct.

### *Gross Negligence*

The Board alleged in its amended complaint that the Apothecary was guilty of gross negligence. Gross negligence is a deviation from professional standards so egregious that it demonstrates a conscious indifference to a professional duty.<sup>31</sup> However, the Board introduced no evidence regarding what that professional duty was. Therefore, we find no gross negligence committed by Pironis or the Apothecary, and therefore find no ground for discipline against the Apothecary for gross negligence.

### *Misrepresentation and Fraud*

Misrepresentation is a falsehood or untruth made with the intent and purpose of deceit.<sup>32</sup> Pironis made no misrepresentation with regard to the April 29 incident. The Board also argues in its brief<sup>33</sup> that Pironis and the Apothecary committed fraud. Fraud is “an intentional perversion of truth to induce another ... to act in reliance upon it.”<sup>34</sup> However, the Board did not allege fraud in its amended complaint. Even if it had been alleged, we find no intent, no perversion of truth, and no inducement to act in reliance upon anything Pironis or the Apothecary communicated. We also find no falsehood or untruth uttered by Pironis or the Apothecary. We find no ground for discipline against the Apothecary for misrepresentation or fraud.

### *Conclusion Regarding § 338.055.2(5)*

We find no ground for discipline against the Apothecary under § 338.055.2(5).

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<sup>31</sup> *Duncan v. Missouri Bd. for Arch'ts, Prof'l Eng'rs & Land Surv'rs*, 744 S.W.2d 524, 533 (Mo. App., E.D. 1988).

<sup>32</sup> MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 794 (11th ed. 2004).

<sup>33</sup> ¶ 64.

<sup>34</sup> *Hernandez v. State Bd. of Regis'n for the Healing Arts*, 936 S.W.2d 894, 899 n.2 and n.3 (Mo. App. W.D. 1997).

### Section 338.055(6) & (15)- Violation of Laws and Regulations

The Board alleged that Pironis violated the following statutes and regulations, and under § 338.210.5, the Apothecary's permit may therefore be subjected to discipline.

#### *Application of § 338.210.5*

Section 338.210.5 provides:

If a violation of this chapter or other relevant law occurs in connection with or adjunct to the preparation or dispensing of a prescription or drug order, any permit holder or pharmacist-in-charge at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation.

If a law was violated, the violation occurred “in connection with or adjunct to the preparation or dispensing of a prescription or drug order.” Therefore, we may deem the Apothecary's permit subject to discipline for such acts, if they occurred in connection with or adjunct to the preparation or dispensing of a drug order. All the acts at issue here occurred in connection with or adjunct to such preparation and dispensing.

#### *Section 338.010*

Section 338.010 defines the practice of pharmacy in relevant part as follows:

The “practice of pharmacy” means the...receipt, transmission, or handling of [medical prescription] orders or facilitating the dispensing of such orders;...the compounding, dispensing, [and] labeling...of drugs...pursuant to medical prescription orders;...and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy. No person shall engage in the practice of pharmacy unless he is licensed under the provisions of this chapter.

Stratman, a pharmacy technician, compounded the chemotherapy drug order. Someone other than Pironis at the Apothecary labeled the order, and someone at the Apothecary dispensed the order. None of these things was done by Pironis or under his supervision. Therefore, if the statute is read alone, Stratman (and any other employees of the Apothecary who dispensed the

product) practiced pharmacy without a license. A pharmacy technician such as Stratman is, by statutory definition, a person who assists a pharmacist in the practice of pharmacy.<sup>35</sup>

Furthermore, some of the Regulations Apothecary is accused of violating expressly permit someone other than a licensed pharmacist to compound,<sup>36</sup> dispense,<sup>37</sup> or label<sup>38</sup> a drug, medicine, or poison, so long as the product is inspected and verified by a licensed pharmacist. Clearly, then, the Board's Regulations contemplate that non-pharmacists, and non-licensed pharmacists, may compound, dispense, and label drugs, medicines, or poisons, so long as their products are inspected and verified by a licensed pharmacist.

We read 20 CSR 2220-2.010(1) (which we discuss in more detail below) as creating conditions under which a pharmacist's supervision of others actually doing the compounding and dispensing, and testing of the final product before it is dispensed, constitutes the practice of pharmacy so as to satisfy § 338.010, even if the pharmacist did not do the compounding and dispensing him or herself. However, Pironis did not supervise and test the product as the Regulation requires. Therefore, we conclude that Stratman engaged in the unlicensed practice of pharmacy by her actions of April 29, 2011, did so at Pironis's instruction, and therefore the Apothecary violated § 338.010.

#### *Section 338.250*

In its complaint against the Apothecary, the Board stated, without explanation or allegation, the following portion of § 338.250:

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<sup>35</sup> Section 338.013.1.

<sup>36</sup> “*Whenever, in a pharmacy or other establishment holding a Missouri pharmacy permit, a person other than a licensed pharmacist does compound, dispense or in any way provide any drug, medicine or poison pursuant to a lawful prescription, a licensed pharmacist must be physically present within the confines of the dispensing area, able to render immediate assistance and able to determine and correct any errors in the compounding, preparation or labeling of that drug, medicine or poison before the drug, medicine or poison is dispensed or sold.*” 20 CSR 2220-2.010(1)(B). (Emphasis added.)

<sup>37</sup> *Id.*

<sup>38</sup> “The pharmacist personally shall inspect and verify the accuracy of...the label after it is affixed to, any prescribed drug, medicine or poison compounded or dispensed by a person other than a licensed pharmacist.” *Id.*

Any pharmacy that receives or possesses drugs or devices shall be held responsible for compliance with all laws within this chapter as well as state and federal drug laws on all drugs received or possessed, including but not limited to drugs and devices received or possessed pursuant to a consignment arrangement.

It repeated the quotation of that statute in its brief. In neither document, however, did the Board allege how the Apothecary may have violated this statute, or otherwise state how it wants us to apply it, and it is not obvious to us. Therefore, we find no violation of § 338.250.

*20 CSR 2220-2.010(1)*

The Board argues that the Apothecary violated 20 CSR 2220-2.010(1), which provides in relevant part:

(1) The word medicine or medicines is a word similar or of like import to the words pharmacist, pharmacy, apothecary shop, chemist shop, drug store, druggist and drugs, and no person shall carry on, conduct or transact a business under a name which contains, as part of the name, the word medicine or medicines, unless the place of business is supervised by a licensed pharmacist.

(A) At all times when prescriptions are compounded in a pharmacy or other establishments holding a Missouri pharmacy permit, there shall be on duty and present in that place of business a pharmacist licensed in Missouri as provided by law. In any Class J: Shared Service pharmacy where a permit is maintained at a location for the purpose of remote dispensing as defined in 20 CSR 2220-2.900 the pharmacist may be considered on duty and present as long as all required electronic connection requirements are maintained and the pharmacist is accessible at all times to respond to patients or other health professionals' inquiries or requests pertaining to drugs dispensed through the use of the automated pharmacy system. When there is no pharmacist on duty, no prescription will be compounded, dispensed or otherwise provided and the public will be advised that no pharmacist is on duty by means of signs stating this fact. The signs will be displayed prominently on the doors of all entrances and the prescription counter of the pharmacy and the signs will be composed of letters of a minimum height of two inches (2").

(B) Whenever, in a pharmacy or other establishment holding a Missouri pharmacy permit, a person other than a licensed pharmacist does compound, dispense or in any way provide any

drug, medicine or poison pursuant to a lawful prescription, a licensed pharmacist must be physically present within the confines of the dispensing area, able to render immediate assistance and able to determine and correct any errors in the compounding, preparation or labeling of that drug, medicine or poison before the drug, medicine or poison is dispensed or sold. In any Class J: Shared Service pharmacy where a permit is maintained at a location for the purpose of remote dispensing as defined in 20 CSR 2220-2.900 the pharmacist may be on duty and present as long as all required electronic connection requirements are maintained and the pharmacist is accessible at all times to respond to patient's or other health professionals' inquiries or requests pertaining to drugs dispensed through the use of the automated pharmacy system. The pharmacist personally shall inspect and verify the accuracy of the contents of, and the label after it is affixed to, any prescribed drug, medicine or poison compounded or dispensed by a person other than a licensed pharmacist.

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(O) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.

Paragraph (A) requires a pharmacist to be on duty and present *in the pharmacy* whenever prescriptions are compounded in the pharmacy. Paragraph (B) requires a pharmacist to be *physically present within the confines of the dispensing area* when a person other than a pharmacist compounds, dispenses, or in any way provides any drug, medicine, or poison pursuant to a lawful prescription. (Emphasis added.) Paragraph (B) also requires the pharmacist to “personally...inspect and verify the accuracy of the contents of, and the label after it is affixed to, any prescribed drug, medicine or poison compounded or dispensed by a person other than a licensed pharmacist.” Paragraph (O) makes the permit holder subject to discipline when it knows or should have known that an employee has violated the pharmacy laws or rules.

In *Board of Pharmacy v. Jack A. Levison & Forum Center Pharmacy*,<sup>39</sup> Levison was the pharmacist-in-charge for Forum Center Pharmacy when an unlicensed person filled two prescriptions while he (Levison) was away from the pharmacy. Also, while Levison was away from the pharmacy, several other errors were made. While the Board alleged a violation of 4 CSR 220-2.010(1)(B),<sup>40</sup> this Commission found that Levison did not know that the unlicensed person filled the prescriptions in his (Levison's) absence. Therefore, we held that Levison was not subject to discipline under 338.055.2(6) or (10) because he did not assist or enable the unlicensed person to violate the regulation.

In this case, however, Pironis not only knew that Stratman was compounding and dispensing a prescription in his absence, but she did those things at Pironis's instruction. Furthermore, both paragraphs (A) and (B) required Pironis to be physically present in the pharmacy (paragraph (A)) and within the confines of the dispensing area when Stratman compounded the drug (paragraph (B)). Pironis was neither in the Apothecary's dispensing area, nor anywhere else in the Apothecary, when Stratman was compounding and dispensing the chemotherapy drug. As applied to the Apothecary, it is deemed liable for Pironis's violation of this Regulation pursuant to § 338.210.5. Finally, Pironis's knowledge of these matters was imputed to the Apothecary,<sup>41</sup> thus rendering the Apothecary's permit subject to discipline pursuant to 20 CSR 2220-2.010(1)(O).

*20 CSR 2220-2.200(12)(A)*

The Board argued in its brief<sup>42</sup> that Pironis violated Regulation 20 CSR 2220-2.200(12)(A), which provides:

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<sup>39</sup> No. 94-001353PH (Missouri Admin. Hearing Comm'n, Jan. 18, 1995).

<sup>40</sup> The predecessor regulation to 20 CSR 2220-2.010(1)(B).

<sup>41</sup> See *Sequa Corp. v. Cooper*, 128 S.W.3d 69, 76 (Mo. App., E.D. 2003) (agent's knowledge of any matter over which his authority reaches is imputed to the principal).

<sup>42</sup> ¶ 25.



#### End-Product Evaluation.

(A) Risk Level 1: The final product must be inspected for container leaks, integrity, solution cloudiness or phase separation, particulates in solution, appropriate solution color, and solution volume. The pharmacist must verify that the product was compounded accurately as to the ingredients, quantities, containers, and reservoirs. Background light or other means for the visual inspection of products for any particulate and/or foreign matter must be used as part of the inspection[.]

The Board argued that Pironis and the Apothecary violated this regulation by allowing technicians to work in the pharmacy without a licensed pharmacist present. We agree insofar as Pironis is concerned—the requirement that a pharmacist “verify that the product was compounded accurately as to the ingredients, quantities, containers, and reservoirs” was not met. However, the Board failed to allege in its amended complaint that the Apothecary violated the regulation.

#### *20 CSR 2220-2.400(8)(A)*

The Board argued in its brief that the Apothecary violated this regulation, but failed to plead it in its amended complaint.

#### *20 CSR 2220-2.700(1)*

The Board’s brief argued that the Apothecary also violated the regulation, but its amended complaint against the Apothecary makes no such allegation.

#### *Conclusion regarding § 338.055.2(6) and (15)*

The Apothecary’s permit is subject to discipline under § 338.055.2(6) and (15) for Pironis’ violation of § 338.010 and 20 CSR 2220-2.010(1)(O).

#### Section 338.055.2(10)- Assisting or Enabling any Person to Practice Pharmacy who is not Eligible to do so

Section 338.055.2(10) states that a pharmacy’s permit may be disciplined for:

Assisting or enabling any person to practice or offer to practice any profession licensed or regulated by this chapter who is not registered and currently eligible to practice under this chapter[.]

As we discuss above under “Section 338.010,” Pironis allowed Stratman, a pharmacy technician and not a pharmacist, to practice pharmacy as it is defined in § 338.010. Furthermore, she practiced pharmacy under Pironis’s direction and with his approval. The Apothecary’s permit is therefore subject to discipline under § 338.210.5 as discussed above, as applied to § 338.055.2(10).

#### Section 338.055.2(13)- Professional Trust or Confidence

The Board alleges that the Apothecary’s permit is subject to discipline for violation of patients’ trust or confidence. Professional trust is the reliance on the special knowledge and skills that professional licensure evidences.<sup>43</sup> It may exist not only between the professional and his clients, but also between the professional and his employer and colleagues.<sup>44</sup> Because we have no evidence that Dr. Hopkins’ patient had any relationship or communication with Pironis or the Apothecary, our inquiry is limited to the relationship the Apothecary had with Dr. Hopkins.

We find no violation of professional trust here. To the contrary, Pironis alerted Dr. Hopkins of the issue and tried to persuade the doctor to seek the drug elsewhere, and when that did not work, accommodated the doctor’s wishes to obtain the drug that day.

The Apothecary’s permit is not subject to discipline under § 338.055.2(13).

#### Other Unpleaded Conduct

In addition to the unpleaded conduct discussed above, the Board’s brief raised several accusations of conduct that it asserted were grounds for discipline, but were not pleaded in its

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<sup>43</sup> *Trieseler v. Helmbacher*, 168 S.W.2d 1030, 1036 (Mo. 1943).

<sup>44</sup> *Cooper v. Missouri Bd. of Pharmacy*, 774 S.W.2d 501, 504 (Mo. App., E.D. 1989).

amended complaint—or, in some cases, were not pleaded for anything other than the September 21 incident, which was not considered by us once we disallowed evidence in support thereof. We set those unpleaded instances out below.

*Alleged Violation of 20 CSR 2220-2.018(1)*

The Board’s brief argued that Pironis directed the Apothecary’s pharmacy technicians to violate 20 CSR 2220-2.018(1) in that “the initials or name of the pharmacist responsible for processes in dispensing or compounding of the prescription” were not affixed to the prescription.<sup>45</sup> However, violation of this Regulation was not pleaded as a ground for discipline.

*Respondents allegedly kept inaccurate and incomplete compounding logs.*

The Board’s brief argued that Respondents allegedly kept inaccurate and incomplete compounding logs.<sup>46</sup> In addition to presenting no evidence in support of this allegation with regard to the April 29 incident, it failed to allege this in its amended complaint.

*Pironis allegedly caused the Apothecary to violate § 195.060.1.*

The Board’s brief argued that Pironis caused the Apothecary to violate § 195.060.1.<sup>47</sup> However, the Board did not allege this in its complaint against Pironis.

*It was Pironis’s alleged “habit, routine, and practice” to violate Missouri law.*

The Board’s brief argued that Pironis had the “habit, routine, and practice” to violate Missouri law.<sup>48</sup> This allegation arose from Pironis’s testimony that, by the Board’s interpretation, the April 29 incident was not the first time one of the Apothecary’s technicians had compounded and dispensed a product without his participation. However, we note (as the Board did not) that Pironis clarified his testimony, stating that while the technicians might have

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<sup>45</sup> Board’s brief ¶ 56.

<sup>46</sup> *Id.* ¶ 39.

<sup>47</sup> *Id.* ¶ 49-50.

<sup>48</sup> *Id.* ¶¶ 50-54.

compounded a product while he was at lunch, the product was never dispensed without his checking it.<sup>49</sup> In any case, the Board failed to allege this matter in its complaint against Pironis.

*The Apothecary allegedly demonstrated unethical and unprofessional conduct in knowingly directing technicians to practice pharmacy.*

The Board's brief made this argument. However, it was not only not raised in either complaint, but the Board failed to state how it constituted grounds for discipline. Our review of the relevant laws also failed to find any such ground.

*The Apothecary allegedly violated 21 U.S.C. §§ 331 and 353(b).*

The Board made this argument in its brief, but did not plead it.

### **Summary**

We find cause to discipline the Apothecary's permit under § 338.055.2(6), (10), and (15). We find no cause to discipline its permit under § 338.055.2(5) or (13), or under the various alleged but unpleaded grounds for discipline.

SO ORDERED on November 6, 2013.

\s\ Marvin O. Teer, Jr  
MARVIN O. TEER, JR.  
Commissioner

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<sup>49</sup> Tr. 134.